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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/215,095	12/18/98	BECKER N	GC507-2

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EXAMINER	
BORIN, M	
ART UNIT	**PAPER NUMBER**
1631	17

DATE MAILED: 03/05/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/215,095	Applicant(s) Becker et al
	Examiner Michael Borin	Group Art Unit 1631

☒ Responsive to communication(s) filed on *Oct 31, 2000*.

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *66-88* is/are pending in the application.

Of the above, claim(s) *70, 71, and 77* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *66-69, 72-76, and 78-88* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. The request for a continued prosecution application (CPA) under 37 CFR 1.53(d) filed on 10/31/2000 is acknowledged. 37 CFR 1.53(d)(1) was amended to provide that the prior application of a CPA must be: (1) a utility or plant application that was filed under 35 U.S.C. 111(a) before May 29, 2000, (2) a design application, or (3) the national stage of an international application that was filed under 35 U.S.C. 363 before May 29, 2000. *See Changes to Application Examination and Provisional Application Practice*, interim rule, 65 *Fed. Reg.* 14865, 14872 (Mar. 20, 2000), 1233 *Off. Gaz. Pat. Office* 47, 52 (Apr. 11, 2000). Since a CPA of this application is not permitted under 37 CFR 1.53(d)(1), the improper request for a CPA is being treated as a request for continued examination of this application under 37 CFR 1.114. *See id.* at 14866, 1233 *Off. Gaz. Pat. Office* at 48.

Status of the claims

2. Claims 1-65 are canceled. Claims 66-88 are added. Claims 66-88 are pending.

It is noted that a new set of claims combines Groups II (compositions of protein, sugar and polysaccharide) and IV (compositions of protein, sugar alcohol and polysaccharide) defined in the original restriction requirement. Upon reconsideration, the restriction requirement is replaced with election of species requirement, wherein the species are sugars and sugar alcohols. As applicant originally elected Group II, sugars are constructively elected as elected species. Claims 70, 71, 77

are withdrawn from consideration as drawn to non-elected species. Claims 66-69, 72-76, 78-88 are examined.

Claim Rejections - 35 USC § 102 and 103.

3. Claims 66-69, 72,74,78,79,82-86 are rejected under 35 U.S.C. 102(b) as anticipated by Kiesser et al. (US Patent 5,739,091)

Kiesser

Kiesser et al. teach enzyme granules. The granules comprise enzyme or enzyme mixture, sugars, such as mono- or di- saccharides, and a filler, such as cellulose. See column 1, lines 31-39, 60-67, column 2, line 66 to col. 3, line 4. The granules may further comprise binders, such as polyethyleneglycol. See col. 2, lines 16-24. The granules may be covered with a protective coating (col.4, lines 5-11). The coating can contain sugars (col. 4, lines 8-10) or polyethyleneglycol (col.4, line 46). The granules may be prepared by layering the enzyme around dry pre-mix. See col. 4, lines 21-24.

It is the Examiners position that all the elements of Applicant's invention with respect to the specified claims are instantly disclosed by the teaching of the reference cited above.

4. Claims 75,76,80,81,87,88 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kiesser et al. (US Patent 5,739,091). The reference is used as applied to claims 66-69,

72,74,78,79.82-86 in the preceding paragraph. The reference does not teach all particular enzymes and all particular cellulose-derived fillers as instantly claimed. Selection of particular enzymes would be *prima facie* obvious as the reference teaches enzyme granules in general and is not limited to any particular enzyme. As for selection of filler, as cellulose derivatives are well know to be used for this purpose, selection of a particular cellulose derivative would be obvious for an artisan to be achieved in a way of ordinary optimization.

5. Claims 66-69,72-74,76, 78-86 are rejected under 35 U.S.C. 103(a) as obvious over Scott (EP 272923).

Scott

Scott teaches granules including enzyme(glucose oxidase), sugar (glucose), low molecular weight polysaccharide (e.g., cellulose), and optionally synthetic polymer. The reference does not teach forming a granule over a seed particle and the presence of a coating layer over the granule. If there are any differences between Applicant's claimed methods and that of the prior art, the differences would be appear minor in nature. Although Scott does not not teach protein core layered over a seed particle and coating the particle, it would be conventional and within the skill of the art to prepare such granule because the techniques of using a seed particle for the intended purpose of forming a granule and coating the granule to protect its content are well known in the pharmaceutical art, and are within the skill in the art to which this invention pertains.

Further, in regard to claims 78-81,84, the use of coating on granules for pharmaceutical or biochemical applications is notoriously well known in prior art.

6. Claims 66-69, 72-76, 78-88 are rejected under 35 U.S.C.103(a) as obvious over Martussen (EP 304332).

Martussen

Martussen teaches enzyme granules comprising an enzyme core surrounded by a coating comprising cellulose or artificial binders. The granules further comprise a binder, such as polyvinyl pirrolidone, cellulose derivatives, etc., and a granulating agent, such as polyglycols. See abstract, pages 2-3. The referenced granule does not contain sugar and polysaccharide. However, addition of such ingredients would be *prima facie* obvious when the enzyme granulates are to be used as nutrient additives, because the reference teaches that in such cases the core could contain sugar, or starch, or protein. See p. 2, lines 32-34.

Further, in regard to seed particle limitation, the difference between the claimed and referenced product would be appear minor in nature. Although the prior art does not not teach protein core layered over a seed particle, it would be conventional and within the skill of the art to prepare such granule because the techniques of using a seed particle for the intended purpose of forming a granule is well known in the pharmaceutical art, and are within the skill in the art to which this invention pertains.

Conclusion.

7. No claims are allowed.

8. All claims are drawn to the same invention claimed in the application prior to the entry of the preliminary amendment and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (703) 305-4506. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If

attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (703) 308-4028. The fax telephone number for this group is (703) 305-3014.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

February 27, 2001

mlb

MICHAEL BORDEN, PH.D.
PATENT EXAMINER